



Position paper on the revision of the Machinery Directive

04/02/2019

In May 2018 the European Commission published a [Staff Working Paper on the evaluation of the Machinery Directive](#) (2006/42/EC). The evaluation overall conclusion is that the Machinery Directive is fit for purpose and that it has coped well with technological developments. This is due to the “New Approach” principles underpinning the Directive. These principles establish that the Directive defines mandatory essential health and safety requirements, leaving the definition of technical details to meet those requirements to harmonised standards developed by stakeholders in line with technological developments and the state-of-the-art.

The next step in the evaluation of the Directive will be the launch of an impact assessment study to evaluate different options in relation to a possible revision of the Directive. According to the Commission [Inception Impact Assessment](#), the study will give special consideration to “AI systems and robots and to cyber threats” and the possible need to introduce changes in the essential requirements of the Directive to consider new technological developments. The alignment of the Directive with the “new legislative framework” and its transformation into a Regulation will also be among the policy options to be considered by the study.

CECIMO members see some benefit in aligning the Directive with the “new legislative framework” (option 1) and in converting it into a Regulation that would be directly applicable and enforceable in all Member States without the need for national transposition (option 4). Nevertheless, from the point of view of our industry, a non-legislative intervention (option 0) would still ensure an optimal level of protection despite new technological developments. We believe that the essential health and safety requirements of the Directive already provide the necessary framework to ensure that safe products, including new technologies such as Artificial Intelligence (AI), are placed on the market and therefore there is no need to introduce changes in the Directive’s essential requirements (option 2). In relation to option 2 it should also be pointed out that the Directive itself does not prescribe the means in which documentation needs to be made available (digital or paper form). The need to provide documentation in paper form is only specified in the Guide to application of the Machinery Directive. This means that rather than changes in the legal text there is a need for changes in the Guide.

Artificial intelligence

Although Artificial Intelligence (AI) is not new and it has evolved considerably in the last decades, the development of relevant applications in the machine tool and manufacturing technologies sector is limited and still at an early development stage. Those companies that have started to explore the possibilities of such technologies are developing applications mainly for process optimization, predictive maintenance and condition monitoring.

One of the main benefits of applying AI technology to CNC machines is to enable condition monitoring and predictive maintenance. CNC machine tools produce a big amount of data that AI solutions can analyze automatically. Through machine learning AI agents can be trained to know what normal operation is, detect anomalies, identify where the fault lies and offer suggestions from its knowledge database on how to rectify it, helping in this way technicians to take the right decisions.

AI applications can also be used to analyze the data and optimise the process by, for example, optimising the 'tool path'. The way a tool travels through a workpiece is known as the 'tool path'. In the case of complex machines and/or workpieces, this can be optimised by AI analysis of the data, which adjusts the tool path to one that generates the highest productivity level and least wear.

In all these cases AI focuses on well scoped, highly defined solutions that target a specific task. It simply acts upon and is bound by a pre-determined, pre-defined range imposed to it by human beings. This is what we call "Narrow/Weak AI", which is the AI that currently exists and on which applications in our sector will be based in the foreseeable future.

It is therefore important that a clear definition of AI based on facts and on what is actually possible rather than misconceptions is used when carrying out the Impact Assessment study of the Machinery Directive. To this respect it is important to follow the work of both the Commission [High-Level Expert Group on Artificial Intelligence](#) and the developments at [ISO/IEC JTC 1/SC 42 "Artificial Intelligence"](#), which is working on concepts and definitions in relation to AI.

From the perspective of the machine tool and related manufacturing technologies sector, the essential requirements included in Annex I of the current Machinery Directive already provide the necessary framework to ensure that machinery placed on the market, whether it integrates AI agents or not, is safe.

The Machinery Directive establishes that during the design and manufacture of machinery, the manufacturer shall identify and evaluate all possible hazards by undertaking a risk assessment. The first step in the risk assessment is to determine the limits of machinery including the intended use and the reasonably foreseeable misuse. Machinery including AI is always designed for a specific function and to operate within a pre-defined range and limits set by the manufacturer. AI cannot change the intended use of the machine by itself or perform other tasks than those it has been designed for.

If the machine includes AI agents, the risk assessment will also identify any foreseeable hazards and estimate any possible risks linked to the inclusion of AI in the machine. To this respect, the essential requirements on control systems (Annex I, 1.2) are relevant and applicable independently of whether a control system would be operated by AI functions or in any other way. These requirements already provide a technology neutral robust legal framework to ensure the safety of machinery, which is complemented by harmonised standards that can further define technical requirements considering the state-of-the-art and new technologies.

Cybersecurity

Increasing digitisation of industry means that cybersecurity is becoming a major issue for manufacturers. Machine tool builders are already considering possible cybersecurity risks and implement measures such as special firewalls, virus scanners or password protection of critical data and parameters. To this respect the recently published [ISO/TR 22100-4](#) provides valuable guidance to machinery manufacturers in relation to cybersecurity aspects.

Nevertheless, cybersecurity is an issue involving several actors and it does not only depend on the machine builder but on a wide range of actors including suppliers, software providers and users. It is therefore important to clearly define the responsibility of each actor.

Machine tool builders are system integrators of various mechanical, electrical and IT components and automation systems. In order to be able to provide updated software and hardware components to keep a machine tool at a certain security level over its lifetime, subsystem and components suppliers should also be able to deliver software updates over a certain period. Typically, machine tools have a life span of 15-25 years and some of them still rely on operating systems no longer available.

Users also have an important role to play. To this respect it is important to highlight that a user would need to guarantee access to the machine to update it and that under current contractual frameworks machine tool builders are generally not allowed to make any updates or modification on installed equipment.

The scope of the Machinery Directive is limited to establishing essential requirements for manufacturers placing machinery for the first time in the EU market. The inclusion of cybersecurity requirements in a revised Directive would therefore not lead to an effective approach to cybersecurity and may instead open the way to a situation where different sector specific pieces of legislation include different and inconsistent requirements on cybersecurity. CECIMO's view is that a horizontal approach inspired in the "new legislative framework" would be better suited to provide a clear general framework for cybersecurity and to define the obligations and liability of each actor.

Digital documentation

Option 2 of the Inception Impact Assessment refers to the introduction of changes in the essential health and safety requirements of the Directive "so as to allow digital documentation". To this respect it is important to point out that the Machinery Directive itself does not specify the form (digital or paper) on which documentation needs to be provided. This is only specified in the [Guide to application of the Machinery Directive](#), which establishes that "health and safety related instructions must be supplied in paper form" (§255).

CECIMO believes that manufacturers should be free to choose the best means to provide the required documentation as long as the requirements are fulfilled, and the required information is provided. Nevertheless, rather than a need for modification of the legal text there is a need for updating the Guide to application of the Directive.

About CECIMO

CECIMO is the European Association of the Machine Tool Industries and related Manufacturing Technologies. We bring together 15 national associations of machine tool builders, which represent approximately 1,500 industrial enterprises in Europe, over 80% of which are SMEs. CECIMO covers 98% of the total machine tool production in Europe and about 33% worldwide. It accounts for around 147,000 employees and a turnover of €26 billion in 2017. 77% of CECIMO production is exported, whereas half of it is exported outside Europe.

The machine tool sector is a supplier of high technology manufacturing equipment and products to the European and international manufacturing industries, including automotive, aerospace, ship building, power generation and the medical sectors.

Contact

Maitane Olabarria

Maitane.olabarria@cecimo.eu